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Proposed Registration Decision PRD2013-05

Soybean Oil

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Overview

Proposed Registration Decision for Soybean Oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Scotts Soybean Oil Technical, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use, containing the technical grade active ingredient soybean oil, to kill ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles and spiders on contact inside the home.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Scotts Soybean Oil Technical, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on soybean oil, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on soybean oil, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Soybean Oil?

Soybean oil is the active ingredient in the end-use products Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use. These products rapidly kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish, and spiders on contact when applied directly to these pests as a crack and crevice treatment or spot spray inside the home such as along baseboards or under sinks.

Health Considerations

Can Approved Uses of Soybean Oil Affect Human Health?

Soybean Oil is unlikely to affect human health when it is used according to label directions.

Potential exposure to soybean oil may occur when handling and applying the end-use products Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use, which are proposed as insecticides for killing ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles, and spiders inside the home. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, the active ingredient, soybean oil, was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not a skin or eye irritant, and was not a skin sensitizer. Soybean oil is, however, a priority allergen. Consequently, 'Warning, contains the allergen soy' is required on the technical grade active ingredient and end-use product labels. Both end-use products are expected to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. Both are moderate skin irritants and minimal eye irritants, but are not dermal sensitizers. As a result of the skin irritation, the labels for these end-use products require the hazard signal words, 'WARNING SKIN IRRITANT'.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Risks in Non-Occupational / Consumer Environments

Estimated risk for non-occupational / consumer exposure is not of concern provided that directions specified on the label are observed.

Exposure to individuals coming in contact with Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use is not expected to result in unacceptable risk when used according to the label directions.

Precautionary and hygiene statements on the label are considered sufficient to protect individuals from any unnecessary risk due to consumer exposure.

Environmental Considerations

An environmental assessment was not required for this application

Value Considerations

What Is the Value of Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use?

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use are fast acting products used to kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish and spiders when applied directly to the pest inside the home.

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use contain soybean oil which suffocates the target pest. Since the mode of action is by physical contact (i.e., suffocation), it is unlikely that pests will develop resistance to soybean oil. These products can be used with other pest control practices and products for the labelled pests. They also represent a new non-conventional chemistry for the domestic class market that can be used inside homes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Scotts Soybean Oil Technical and the associated end-use products to address the potential risks identified in this assessment are provided below.

Key Risk-Reduction Measures

Human Health

Since soybean oil is collected from soy, a priority allergen, the principal display panel for the Scotts Soybean Oil Technical and both end-use products require the signal words, "Warning, contains the allergen soy."

The signal words, 'WARNING SKIN IRRITANT' are required on the principal display panels of the labels for the two end-use products. The statements, 'Causes skin irritation. DO NOT get on skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.' are required for the PRECAUTIONS section of the secondary display panel for both end-use products.

Next Steps

Before making a final registration decision on soybean oil, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on soybean oil (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Soybean oil

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	
Function	Insecticide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	No IUPAC name assigned
2. **Chemical Abstracts Service (CAS)**	Soybean oil
CAS number	8001-22-7
Molecular formula	N/A
Molecular weight	N/A
Structural formula	N/A
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Soybean Oil Technical

Property	Result
Colour and physical state	Light yellow liquid
Odour	Odourless
Melting range	N/A
Boiling point or range	>260°C
Specific gravity	0.917 at 25°C
Vapour pressure at 20°C	Expected to be very low
Ultraviolet-visible spectrum	Not established
Solubility in water at 20°C	Negligible < 5%

Property	Result
Solubility in organic solvents at 20°C (g/100 mL)	Expected to be soluble in alcohols and oils.
n-Octanol–water partition coefficient (K_{OW})	Expected to be very low.
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable

End-Use Products

Property	Scotts Ecosense Indoor Insect Killer Aerosol	Scotts Ecosense Indoor Insect Killer Ready-To-Use
Colour	Very pale yellow	White
Odour	Oily odour	Oily odour
Physical state	Liquid suspension	Liquid
Formulation type	Pressurized product	Emulsifiable concentrate
Guarantee	7.5%	7.5%
Container material and description	250g to 1 kg metal aerosol canisters	high-density polyethylene bottles with spritzer applicators, 250 mL to 1 L
Density	0.968–1.008 g/mL at 23°C	0.968–1.008 g/mL at 24°C
pH of 1% dispersion in water	6.9–8.9	6.9–8.9
Oxidizing or reducing action	N/A	N/A
Storage stability	Stable when stored for one year at ambient temperature in commercial packaging.	Stable when stored for one year at ambient temperature in commercial packaging.
Corrosion characteristics	Not corrosive to the container material.	Not corrosive to the container material.
Explodability	Not explosive	Not explosive

1.3 Directions for Use

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use are both domestic class products for application inside homes to rapidly kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish and spiders. The products are to be sprayed directly onto the target pest found in areas such as cabinets, drawers, closets, under sinks, walls, cracks, crevices and baseboards. These products can be applied as necessary. For further information, please refer to the product labels.

1.4 Mode of Action

Soybean oil suffocates the target pest.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Two Association of Analytical Communities official methods were referenced and assessed to be acceptable for the analysis of the technical product.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for soybean oil consisting of peer reviewed published journal articles and foreign reviews was conducted. The scientific quality of the data is acceptable and the database is considered sufficiently complete to define any toxic effects that may result from exposure to soybean oil.

The applicant was not required to submit additional toxicology information for the technical grade active ingredient, Scotts Soybean Oil Technical. Studies were submitted for acute toxicity by the oral, dermal, and inhalation routes, as well as primary skin and eye irritation, and dermal sensitization for each of the two end-use products, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use.

Soybean oil is expected to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a skin or eye irritant, and it is not a skin sensitizer. Soybean oil is, however, a priority allergen. Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use are of low acute toxicity via the oral, dermal, or inhalation routes of exposure, are moderate skin irritants, minimal eye irritants, but are not dermal sensitizers.

Short-term toxicity information available from peer reviewed scientific journal articles for soybean oil included 28 and 90 day repeated dose oral toxicity studies in rats. In the 28 day study, a lowest observed adverse effect level (LOAEL) of >3 g/kg bw/day due to the absence of any treatment related adverse effects. Likewise, there were no treatment related adverse effects to the rats administered 2000 mg/kg bw/day of soybean oil in the 90-day study. The LOAEL was therefore >2000 mg/kg bw/day.

Based on a long history of use of soybean oil in foods and personal products, it is expected that soybean oil is not a developmental toxicant or is genotoxic.

3.2 Occupational and Bystander Risk Assessment

3.2.1 Use Description / Exposure Scenario

The proposed domestic use of Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use is as an aerosol spray and a pump/trigger spray, respectively, to kill ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles, and spiders inside the home. The end-use products are to be applied as required and do not have a defined reapplication interval.

3.2.2 Dermal Absorption

Based on available information, it is not expected that dermal exposure to soybean oil will result in a significant amount being absorbed.

3.2.3 Occupational Exposure and Risk Assessment

The domestic products, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use, do not require mixing or loading, thus occupational exposure and the associated risk assessment is not applicable.

3.2.4 Consumer Exposure and Risk Assessment

Exposure of consumers to Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use is characterized as short and intermediate in duration, and predominantly via the dermal and inhalation routes. Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use contain soybean oil at a guarantee of 7.5 % by weight.

Since no toxicological endpoints of concern were identified, a quantitative risk assessment was not conducted for the proposed use. The potential exposure to soybean oil is considered to be moderate since it is applied within the home and at the discretion of the consumer.

Based on the available information of the toxicology of soybean oil, no adverse effects are expected to occur from the proposed use of Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use when applied in accordance with the label instructions.

3.3 Incident Reports Related to Human and Animal Health

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents were searched and reviewed

for the active ingredient, soybean oil. As of 30 October 2012, there was one human incident involving soybean oil reported to the PMRA, which was minor in severity.

The PMRA concluded that the reported symptoms were not likely caused by a pest control product containing soybean oil. Consequently, the incident did not affect the outcome of the risk assessment.

4.0 Impact on the Environment

An environmental assessment was not required for this application.

5.0 Value

5.1 Effectiveness Against Pests

Three efficacy trials conducted in the laboratory during 2009 and 2010 support the label claims for these products. These trials investigated the efficacy of these products against two genera of ants, three genera of cockroaches, three genera of spiders and one genus each for crickets, earwigs, silverfish and carpet beetle. For all pests, application of both of these products directly to the target pest resulted in 100% mortality within 30 minutes.

5.1.1 Acceptable Efficacy Claims

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use provide rapid knockdown and kill of ants, carpet beetles, cockroaches, crickets, earwigs, silverfish and spiders when these products are applied directly to the pest until thoroughly covered.

5.1.2 Non-Safety Adverse Effects

One trial was submitted which investigated the potential for damage to hardwood flooring, laminate flooring, wallpaper, linoleum, tile, painted drywall, and carpet by soybean oil. After treatment, an oily residue remained on all hard surfaces and a slight odor was detected on the carpet. The residue and odor were removed after cleaning with standard cleaning products and water. No staining was observed on the tested substrates. Precautionary statements are located on the labels of the products to indicate that there is a potential for an oily residue and an odor on carpet after treatment. In addition, the label contains a precautionary statement advising the user to treat a small, inconspicuous area of the surface to be treated to determine if staining or other damage will occur prior to treating the entire area.

5.2 Sustainability

5.2.1 Survey of Alternatives

Pyrethrins and pyrethroids (mode of action group 3A) constitute most of the active ingredients currently registered for the domestic class market to kill the pests listed on the labels of Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use. Most registered pyrethroids and pyrethrins are currently under re-evaluation by the PMRA (REV2011-05, *Re-evaluation of Pyrethroids, Pyrethrins and Related Active Ingredients*).

Boric acid, borax, disodium octaborate tetrahydrate and propoxur are used against most of the pests found on the labels of Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use. However, the proposed re-evaluation decisions for these active ingredients (PRVD2012-03, *Boric Acid and its Salts (Boron)* and PRVD2011-09, *Propoxur*) could result in a reduced number of products available (for example, removal of dust formulations; bait station use only) or active ingredients available in the future.

Other available alternative active ingredients are for use against some of the pests found on the labels of Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use. Silicon dioxide is an alternative active ingredient that is registered against all the pests found on these labels. Chlorpyrifos is registered for use against ants, cockroaches and earwigs but only as a bait formulation. Abamectin can be used as bait against ants and cockroaches. German cockroach extract is registered for use an attractant in a trap against German cockroaches. D-limonene is a non-conventional active ingredient registered for use against cockroaches, crickets and spiders. For further information, refer to Table 3 in Appendix 1.

5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management

Both Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use can be used with other pest control practices (for example, sanitation, structural repairs) against labelled pests.

5.2.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Soybean oil kills listed pests by suffocation Since the mode of action is by physical contact (i.e., suffocation), it is unlikely that pests will develop resistance to soybean oil.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

Soybean oil and the two end-use products, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use were assessed in accordance with the PMRA Regulatory Directive DIR99-03:[5]

- Soybean oil does not meet the Track 1 criteria as the active ingredient is not highly toxic, and is not expected to be persistent in the environment or to bioaccumulate.

- There are also no formulants, contaminants or impurities present in the end-use products, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use that would meet the TSMP Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

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[5] Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.*

[6] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-11-30) pages 2641-2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613: *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[7] Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

[8] Regulatory Directive DIR2006-02, *PMRA Formulants Policy and Implementation Guidance Documents.*

- Soybean oil, Scotts Ecosense Indoor Insect Killer Aerosol, and Scotts Ecosense Indoor Insect Killer Ready-To-Use do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an on-going basis through PMRA formulant initiatives and DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for soybean oil is sufficiently complete to define the majority of toxic effects that may result from exposure to soybean oil. Soybean oil is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a skin or eye irritant, and is not a dermal sensitizer. Soybean oil is of low short-term toxicity, is not associated with prenatal developmental toxicity, and is not genotoxic. Soybean oil is, however, a priority allergen. Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use are expected to have very similar toxicological profiles to soybean oil with the exception that they are, based on the review of data submitted, moderate skin irritants and minimal eye irritants.

Both Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use are to be used as required, thus care is necessary to ensure that incidental dermal exposure is minimized. After use, individuals are instructed to wash thoroughly with soap and water, as well as washing contaminated clothing prior to reuse.

Exposure to individuals handling Scotts Ecosense Indoor Insect Killer Aerosol or Scotts Ecosense Indoor Insect Killer Ready-To-Use is not expected to result in unacceptable risk when the end-use products are used according to label directions.

7.2 Environmental Risk

7.3 Value

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use are fast-acting products used to kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish and spiders when applied directly to the pest inside the home. Pests are unlikely to develop resistance to these products and they can be used with other pest control practices and products for the labelled pests. They also represent a new non-conventional chemistry for the domestic class market that can be used inside homes.

7.4 Unsupported Uses

All uses were supported.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Scotts Soybean Oil Technical, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use containing the technical grade active ingredient soybean oil, to kill ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles, and spiders on contact inside the home.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
bw	body weight
CAS	Chemical Abstracts Service
g	gram
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
mg	milligram
mL	millilitre
N/A	not applicable
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures

Table 1 Summary of Acute Toxicity and Short-Term Toxicity Information for Soybean Oil

STUDY	SPECIES/STRAIN AND DOSES	RESULT	TARGET ORGAN / SIGNIFICANT EFFECTS / COMMENTS	REFERENCE
Acute oral toxicity	Rat — Sprague Dawley (5/sex), 10,000 mg/kg bw	LD_{50} (♂+ ♀) > 10,000 mg/kg bw **Low acute toxicity**	Loose stools and soiled periproctal areas in both sexes..	2271490
Acute dermal toxicity	Based on a long history of use and available information, soybean oil is expected to be of low acute toxicity.			2271512
Acute inhalation toxicity	Based on a long history of use and available information, soybean oil is expected to be of low acute toxicity.			2271512
Primary eye irritation	Based on a long history of use and available information, soybean oil is not expected to be an eye irritant.			2271512
Primary skin irritation	Based on a long history of use and available information, soybean oil is not expected to be a skin irritant.			2271512
Dermal sensitization	Based on a long history of use and available information, soybean oil is not expected to be a skin sensitizer.			2271512
Short-term oral toxicity (28 days)	Rat — Sprague Dawley (10/sex) 3 g/kg bw/day	LOAEL > 3 g/kg bw/day	No treatment related adverse effects.	2271501
Short-term oral toxicity (90 days)	Rat — Sprague Dawley (20/sex) 2000 mg/kg bw/day	LOAEL > 2000 mg/kg bw/day	No treatment related adverse effects.	2271490
Prenatal developmental toxicity	Based on a long history of use and available information, exposure to soybean oil is not expected to result in developmental toxicity.			2271512
Genotoxicity: bacterial reverse mutation assay	Based on a long history of use and available information, soybean oil is not expected to be mutagenic.			2271512
Genotoxicity: *in vitro* mammalian cell assay	Based on a long history of use and available information, soybean oil is not expected to be genotoxic.			2271512

Table 2 Summary of Acute Toxicity Information for Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use

Study	Species/Strain and Doses	Result	Target Organ / Significant Effects / Comments	Reference
Acute oral toxicity	Rat — Sprague Dawley (3 females), 5000 mg/kg bw, up and down procedure	LD_{50} (♀) >5000 mg/kg bw **Low acute toxicity**	No mortality occurred.	2133367
Acute dermal toxicity	Rat — Sprague Dawley (5/sex) 5000 mg/kg bw, limit test	LD_{50} (♂+ ♀) > 5000 mg/kg bw **Low acute toxicity**	Erythema and desquamation was observed in all test animals. No mortality occurred.	2133368
Acute inhalation toxicity	Rat — Sprague Dawley (5/sex), 5.04 mg/L , Nose-only exposure, 4 hr	LC_{50} (♀ + ♂) > 5.04 mg/L **Low acute toxicity**	No mortality occurred.	2133367
Eye Irritation	Rabbit — New Zealand White (1♂ + 2♀) Dose: 0.1 mL of test substance. Eyes were left unwashed.	MIS (1 hr) = 4.67/110 MAS (24, 48, & 72 hrs) = 0/110 **Minimally irritating**	Conjunctivitis cleared by 24 hours.	2133373
Dermal Irritation	Rabbit — New Zealand White (3♀) Dose: 0.5 mL	MIS (1 hr) = 4.0/8 MAS (24, 48, & 72 hrs) = 2.56/8 **Moderately irritating**	Erythema and edema resolved by 7 days.	2133374
Dermal Sensitization Buehler method	Guinea Pig — Hartley Albino (30♂, 10 control/20 test) Induction (0.5 mL): Undiluted test substance Challenge (0.4 mL): 50% in mineral oil	Negative results. **Not a dermal sensitizer**		2133376

MAS = maximum average score
MIS = maximum irritation score

Table 3 Alternative Insecticide Active Ingredients Found in Domestic Class Products to Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use in USC 20: Structural.

Pest	Mode of Action Group	Alternative Insecticide Active Ingredients Include
Ants	1A: Carbamates	Propoxur
	1B: Organophosphates	Chlorpyrifos
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Imiprothrin; Permethrin; Prallethrin; Pyrethrins; Resmethrin; Tetramethrin
	6: Avermectins, Milbemycins	Abamectin
	8D: Borax	Borax
	Other:	Boric acid; Disodium octaborate tetrahydrate; Silica aerogel; Silicon dioxide
Carpet Beetles	1A: Carbamates	Propoxur
	3A: Pyrethroids, Pyrethrins	D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Imiprothrin; Permethrin; Prallethrin; Pyrethrins; Tetramethrin
	Other:	Boric acid; Paradichlorobenzene; Silicon dioxide
Cockroaches	1A: Carbamates	Propoxur
	1B: Organophosphates	Chlorpyrifos
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Imiprothrin; Permethrin; Pyrethrins; Resmethrin; Tetramethrin
	6: Avermectins, Milbemycins	Abamectin
	Semiochemical	German cockroach extract
	Other:	Boric acid; D-limonene; Disodium octaborate tetrahydrate; Silica aerogel, Silicon dioxide
Cricket	1A: Carbamates	Propoxur
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Imiprothrin; Permethrin; Prallethrin; Pyrethrins; Tetramethrin
	Other:	Boric acid; D-limonene; Silicon dioxide
Earwig	1A: Carbamates	Propoxur
	1B: Organophosphates	Chlorpyrifos
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Permethrin; Pyrethrins; Resmethrin; Tetramethrin
	Other:	Boric acid; Silicon dioxide
Silverfish	1A: Carbamates	Propoxur
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-trans allethrin; D-phenothrin; Permethrin; Pyrethrins; Tetramethrin
	Other:	Boric acid; Silica aerogel; Silicon dioxide
Spiders	1A: Carbamates	Propoxur
	3A: Pyrethroids, Pyrethrins	Cyfluthrin; D-cis, trans allethrin; D-phenothrin; D-trans allethrin; Imiprothrin; Permethrin; Prallethrin; Pyrethrins; Resmethrin; Tetramethrin
	Other:	D-limonene; Silicon dioxide

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
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2134047	2011, Detailed Production Process Description, DACO: 2.11.3 CBI
2134048	1997, Moisture Karl Fischer Reagent, DACO: 2.13.1
2134049	1997, Free Fatty Acids, DACO: 2.13.1
2134050	2000, Color, DACO: 2.14.1
2134051	2001, Gardner Color, DACO: 2.14.1
2134052	2011, Scotts Miracle Gro Data Request, DACO: 2.13.2,2.13.3 CBI
2134053	2011, pH, DACO: 2.16 CBI
2134054	2009, Bulk Density/Specific Gravity, DACO: 2.14.6 CBI
2134055	2007, Specific Gravity/Density Procedure, DACO: 2.14.6 CBI
2134056	2011, Appearance, DACO: 2.14.2 CBI
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2195167	2012, Soybean Oil Registration as a Technical Grade Active Ingredient, DACO: 2.11.3 CBI
2260552	2012, Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Specific Gravity, Viscosity and Storage Stability, DACO: 2.14.1,2.14.14,2.14.2,2.14.3,2.14.6 CBI
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2133342	2007, Description of starting materials (CBI removed), DACO: 3.2.1
2133343	2009, Description of starting materials (CBI removed), DACO: 3.2.1
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2133346	2011, Description of starting materials (CBI removed), DACO: 3.2.1

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2133357	2010, Analytical Testing Method, DACO: 3.4.1 CBI
2133358	2011, Scotts EcoSense Indoor Insect Killer Ready-to-Use S-14531. Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction Potential, Flammability, pH, Viscosity, Specific Gravity, Corrosion and Storage Stability, DACO: 3.5.1
2133359	2011, DACO 3.5.12 Explodability for Scotts Ecosense Indoor Insect Killer Aerosol, DACO: 3.5.12 CBI
2133361	2011, DACO 3.5.13 Miscibility for Scotts Ecosense Indoor Insect Killer Aerosol, DACO: 3.5.13 CBI
2133362	2011, DACO 3.5.15_Waiver for Not Submitting Dielectric Breakdown Voltage Data for Scotts Ecosense Indoor Insect Killer Aerosol, DACO: 3.5.15 CBI
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2194117	2012, Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction Potential, Flammability, Flame Extension, pH, Viscosity, Specific Gravity, Corrosion and Storage Stability, DACO: 3.5.10,3.5.14 CBI
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2133816	2011, Description of starting materials (CBI removed), DACO: 3.2.1
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2133826	2011, DACO 3.5.13 Miscibility for Scotts Ecosense Indoor Insect Killer Aerosol, DACO: 3.5.13 CBI
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2133829	2011, DACO 3.5.4 Formulation Type for Scotts Ecosense Indoor Insect Killer Aerosol, DACO: 3.5.5 CBI
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2.0 Human and Animal Health

PMRA Document Number	Reference
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2133367	2011, S-14531 (7.5% Soybean Oil), Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1

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3.0 Environment

4.0 Value

PMRA Document Number	Reference
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2133335	2011, Mode of Action, DACO: 10.2.1
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2159288	2010, Non safety effects data, DACO: 10.3.2
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2133804	2011, Value Summary for Soybean Oil, DACO: 10.1
2133806	2011, Summary of Trials for Soybean Oil RTU and Aerosol Formulations_EXCEL, DACO: 10.1,10.2.3.1
2133807	2011, Mode of Action, DACO: 10.2.1
2133808	2011, Description of Pest Problem, DACO: 10.2.2
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2159169	2010, Project: Soybean Oil Insect Killer RTU and Aerosol, DACO: 10.2.3.2(C)
2159170	2010, Non safety affects data, DACO: 10.3.2
2159171	2008, Soybean Oil Indoor Insect: Stain testing on indoor surfaces, DACO: 10.3.2
2159172	2012, Full Composition Disclosure: Treatments for Insecticide Stain Testing Conducted, DACO: 10.3.2
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B. Additional Information Considered

i) Published Information

1.0 Chemistry

2.0 Human and Animal Health

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3.0 Environment

4.0 Value

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